UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION	)	**MDL 2804**
	)	
	)	**Case No. 1:17-md-2804**
THIS DOCUMENT RELATES TO:	)	
	)	**Judge Dan Aaron Polster**
Track One Cases	)	
	)	**OPINION AND ORDER REGARDING PLAINTIFFS' SUMMARY JUDGMENT MOTIONS ADDRESSING THE CONTROLLED SUBSTANCES ACT**

Before the Court are two related summary judgment motions filed by Plaintiffs: (1) a Motion for Partial Summary Adjudication of Defendants' Duties Under the Controlled Substances Act (**Doc. #: 1887**); and (2) a Motion for Partial Summary Adjudication against Manufacturer and Distributor Defendants (**Doc. #: 1910**).

With the first motion, Plaintiffs ask the Court to determine that, as a matter of law, the Controlled Substances Act ("CSA"), 21 U.S.C. §§ 801 *et seq.*, and its implementing regulations, 21 C.F.R. §§ 1301 *et seq.*, require defendants who are "registrants" to: (1) identify suspicious orders of controlled substances; (2) report to the Drug Enforcement Administration ("DEA") suspicious orders when discovered; and (3) decline to ship a suspicious order unless and until, through due diligence, the registrant can determine the order is not likely to be diverted into illegal channels. For the reasons set forth below, the Court **GRANTS** Plaintiffs' first Motion (Doc. #: 1887).

Exhibit A

Plaintiffs' second Motion goes further and asks the Court to determine that, as a matter of law and undisputed fact, Defendants failed to comply with the three above-listed duties. Because there are material facts in dispute, the Court **DENIES** Plaintiffs' second Motion (Doc. #: 1910). The Court's reasoning and analysis is set forth below.

I. Legal Standard.

The parties have filed about 30 motions seeking summary judgment on various issues and claims. The Court sets out here, in it first summary judgment opinion, the legal standards it will apply when considering all of these motions. The Court will not repeat these legal standards in subsequent opinions, and instead incorporates them by reference in advance.

Pursuant to Rule 56 of the Federal Rules of Civil Procedure, summary judgment is appropriate "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). In reviewing summary judgment motions, the Court must view evidence in the light most favorable to the non-moving party to determine whether a genuine issue of material fact exists. *Adickes v. S.H. Kress & Co.*, 398 U.S. 144 (1970); *CenTra, Inc. v. Estrin*, 538 F.3d 402, 412 (6th Cir. 2008).

A fact is "material" only if its resolution will affect the outcome of the lawsuit. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986); *Daugherty v. Sajar Plastics, Inc.*, 544 F.3d 696, 702 (6th Cir. 2008). Determination of whether a factual issue is "genuine" requires consideration of the applicable evidentiary standards. Thus, in most civil cases, the Court will decide "whether reasonable jurors could find by a preponderance of the evidence that the [non-moving party] is entitled to a verdict." *Anderson*, 477 U.S. at 252. However, if the non-moving party faces a heightened burden of proof, such as clear and convincing evidence, it must show that it can produce

evidence which, if believed, will meet the higher standard. *Street v. J.C. Bradford & Co.*, 886 F.2d 1472, 1479 (6th Cir. 1989).

Upon filing a motion for summary judgment, the moving party has the initial burden of establishing there are no genuine issues of material fact as to an essential element of the claim or defense at issue. *Street v. J.C. Bradford & Co.*, 886 F.2d 1472, 1479-80 & n.12 (6th Cir. 1989); *Chappell v. City of Cleveland*, 584 F. Supp. 2d 974, 988 (N.D. Ohio 2008). The moving party, however, is not required to file affidavits or other similar materials negating a claim on which its opponent bears the burden of proof, so long as the moving party relies upon the absence of the essential element in the record. *Celotex Corp. v. Catrett*, 477 U.S. 317 (1986); *Chappell*, 584 F. Supp. 2d at 987.

In response, the non-moving party may not rely merely on allegations or denials in its own pleading; rather, its response must set out specific facts showing a genuine issue for trial. *See* Fed. R. Civ. P. 56(e); *see also Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586-87 (1986). In this regard, "Rule 56 does not impose upon the district court a duty to sift through the record in search of evidence to support a party's opposition to summary judgment"; rather, "Rule 56 allocates that duty to the opponent of the motion, who is required to point out the evidence, albeit evidence that is already in the record, that creates an issue of fact." *Williamson v. Aetna Life Ins. Co.*, 481 F.3d 369, 379-80 (6th Cir. 2007) (citation omitted); *see* Fed. R. Civ. P. 56. Moreover, the non-moving party must show more than a scintilla of evidence to overcome summary judgment; it is not enough for the non-moving party to show that there is some metaphysical doubt as to material facts. *Matsushita Elec. Indus. Co.*, 475 U.S. at 586-87; *see also Barr v. Lafon*, 538 F.3d 554, 574 (6th Cir. 2008).

Accordingly, the ultimate inquiry is whether the record as a whole, when viewed in the light most favorable to the non-moving party, could lead a rational trier of fact to find in favor of the non-moving party. *Matsushita Elec. Indus. Co.*, 475 U.S. at 586-87; *see also Anderson*, 477 U.S. at 252 ("The judge's inquiry, therefore, unavoidably asks whether reasonable jurors could find by a preponderance of the evidence that the [non-moving party] is entitled to a verdict – whether there is [evidence] upon which a jury can properly proceed to find a verdict for the party producing it, upon whom the onus of proof is imposed."). If, after reviewing the record as a whole, a rational fact-finder could not find for the nonmoving party, summary judgment is appropriate since there is no genuine issue of material fact for determination at trial. On the other hand, if a reasonable jury could return a verdict for the nonmoving party, summary judgment for the moving party is inappropriate. *Baynes v. Cleland*, 799 F.3d 600, 606 (6th Cir. 2015) (citing *Anderson*, 477 U.S. at 248.

When the movant requests the Court to make a purely legal determination, it need not delve into factual disputes. *See, e.g., Chernin v. Welchans*, 641 F. Supp. 1349, 1358 (N.D. Ohio 1986) (factual disputes are not "material" where determination of the constitutionality of a law on its face is a legal, not factual, determination).

II. Analysis.

The Court's analysis of Plaintiffs' Motions begins with the CSA itself and the DEA's implementing regulations. The Court then examines case law applying this statute and regulations. Because the parties cite them, the Court also reviews two letters issued by the DEA that discuss the CSA and the DEA's regulations; but the Court does not rely upon these letters to determine what duties the law imposes upon the defendants. The Court also re-adopts more fully Discovery

Ruling No. 12 in this case, which examined earlier in this case (in a different context) the duties imposed upon Defendants under the CSA.

Finally, at the end of this Order, the Court examines what the Defendants actually did compared to what the law requires.

A. CSA Statutory and Regulatory Framework.

The CSA requires all manufacturers and distributors of certain controlled substances to register with the DEA. *See* 21 U.S.C. §§ 822, 823. Under Section 823, the DEA shall register an applicant unless it determines that issuing the registration is "inconsistent with the public interest." 21 U.S.C. §§ 823(b), (d), and I. In addition, the DEA may revoke a registration upon finding that the registrant has committed acts that would render its registration "inconsistent with the public interest." 21 U.S.C. § 824(a)(4).

In determining the public interest, the DEA Administrator considers the following factors:

> (21) maintenance of effective control against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels;
>
> (2) compliance with applicable State and local law;
>
> (3) prior conviction record of applicant under Federal or State laws relating to the manufacture, distribution, or dispensing of such substances;
>
> (4) past experience in the distribution of controlled substances; and
>
> (5) such other factors as may be relevant to and consistent with the public health and safety.

21 U.S.C. §§ 823(b), (d), and (e).[1]

[1] Regarding registration of manufacturers of controlled substances in schedule I or II, the DEA shall register an applicant if it determines that such registration is "consistent with the public interest." 21 U.S.C. § 823(a). Slightly different factors apply when determining the public interest under this provision. *See id.*

The CSA authorizes the DEA "to promulgate rules and regulations . . . relating to the registration and control of the manufacture, distribution, and dispensing of controlled substances…."[2] 21 U.S.C. § 821. Pursuant to this authorization, the DEA has promulgated regulations that set forth security requirements for registered manufacturers, distributors, and dispensers of controlled substances. *See* 21 C.F.R. §§ 1301.71-77. Sections 1301.71 and 1301.74 apply to plaintiffs' arguments in this case.[3] Specifically, Section 1301.71(a) states as follows:

> All applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances. In order to determine whether a registrant has provided effective controls against diversion, the Administrator shall use the security requirements set forth in §§ 1301.72 − 1301.76 as standards for the physical security controls and operating procedures necessary to prevent diversion. * * *

21 C.F.R. § 1301.71(a).[4]

Section 1301.74(b) states as follows:

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[2] The CSA authorizes the Attorney General to regulate the distribution of controlled substances. In turn, the Attorney General has delegated his authority to the DEA Administrator. *See John Doe, Inc. v. Gonzalez*, 2006 WL 1805685 at *1 (D.C. Cir. June 29, 2006; *United States v. Caudle*, 828 F.2d 1111, 1111 n.1 (5th Cir. 1987) (citing 38 Fed. Reg. 18380 (1973)).

[3] The other regulations deal primarily with physical security controls and/or security controls for practitioners and freight forwarding facilities. *See* 21 C.F.R. §§ 1301.72 (physical security controls for non-practitioners); 1301.73 (additional physical security controls for non-practitioners); 1301.75 (physical security controls for practitioners); 1301.76 (other security controls for practitioners); 1301.77 (security controls for freight forwarding facilities).

[4] After evaluating the overall security system and needs of an applicant or registrant, the DEA Administrator may deem substantial compliance sufficient. 21 C.F.R. § 1301.71(b). In determining the need for strict compliance with security requirements, the Administrator may consider any of the 15 factors listed in Section 1301.71(b). *See* 21 C.F.R. § 1301.71(b). Those factors include, *inter alia*, the type of activity conducted; the type and form of controlled substances handled; the quantity of controlled substances handled; and the adequacy of the registrant's system for monitoring the receipt, manufacture, distribution, and disposition of controlled substances in its operations. *See* 21 C.F.R. §§ 1301.71(b)(1), (2), (3), and (14).

> The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

21 C.F.R. § 1301.74(b).

B. Case Law.

1. DEA ruling in *Southwood Pharmaceuticals.*

In 2007, the DEA Deputy Administrator issued an administrative decision and final order revoking the registration of Southwood Pharmaceuticals, Inc. to manufacture controlled substances. *See Southwood Pharmaceuticals, Inc.*, 72 Fed. Reg. 36487-01, 36498, 2007 WL 1886484 (DEA July 3, 2007). In December of 2005, Southwood had begun selling large quantities of hydrocodone to internet pharmacies, many of which were dispensing illegal prescriptions for controlled substances. *Id.* at 36488-36491. At the time, Southwood did not re-evaluate its criteria and procedures to determine whether these orders were suspicious; without inquiring into the nature of their internet businesses, Southwood sold its new customers large quantities of hydrocodone. *Id.* at 36496. Moreover, after learning substantial information which raised serious doubt as to the legality of their businesses, Southwood continued to supply extraordinarily large quantities of hydrocodone to these internet pharmacies. *Id.* at 36498-36500.

The Deputy Administrator found that Southwood's due diligence efforts were "wholly deficient." *Id.* at 36498. Specifically, the Deputy Administrator found that Southwood "failed miserably to conduct adequate due diligence" and "did not stop selling to any of its internet pharmacy customers while it investigated the legitimacy of their [business] activities." *Id.* at 36500. Based on Southwood's inadequate due diligence measures and repeated failure to report

suspicious orders, the Deputy Administrator concluded that to allow Southwood's registration to continue would be "inconsistent with the public interest." *Id.* at 36500-36501 (quoting 21 U.S.C. § 824(a)(4)). The DEA revoked Southwood's registration to distribute controlled substances because its distribution was not, in fact, adequately "controlled."

2. DEA ruling in *Masters Pharmaceutical* ("*Masters I*").

In 2015, the DEA Acting Administrator issued an administrative order revoking the registration of Masters Pharmaceutical, Inc. to distribute controlled substances. *See Masters Pharmaceutical, Inc.* ("*Masters I*"), 80 Fed. Reg. 55418-01, 2015 WL 5320504 (DEA Sept. 15, 2015). Over the course of several years, Masters had repeatedly ignored and failed to investigate or report hundreds of suspicious orders and continued to ship them anyway. *See id.* at 55426-55472. Based on its "wholesale failure" to comply with the requirements of Section 1301.74(b), the Acting Administrator found that Masters had committed acts that rendered its registration "inconsistent with the public interest." *Masters I*, 80 Fed. Reg. 55418-01, 55501 (quoting 21 U.S.C. § 824(a)(4)).

The Acting Administrator found that, in *Southwood*, the DEA had made clear to registrants that to comply with the duty to maintain effective controls against diversion, a distributor must perform due diligence on its customers. *Masters I*, 80 Fed. Reg. 55418-01, 55477 (citing *Southwood*, 72 Fed. Reg. 36487-01, 36,498). The Acting Administrator further found that, when a registrant has obtained information that an order is suspicious, but chooses to ignore that information and fails to report the order, it violates its duties under Section 1301.74. *See Masters I*, 80 Fed. Reg. 55418-01, 55478. And while a distributor may perform due diligence and properly conclude that an order initially flagged as suspicious is not suspicious after all, in order to render

the order non-suspicious and exempt the distributor from the DEA's mandatory reporting and no-shipping requirements, "the investigation must dispel all red flags indicative that a customer is engaged in diversion." *Id.* In other words, if, after investigating, the distributor has "any remaining basis to suspect that a customer is engaged in diversion," it must deem the order suspicious, inform the DEA, and decline to ship the order. *Id.*

3. D.C. Circuit ruling in *Masters Pharmaceutical* ("*Masters II*").

Masters petitioned the United States Court of Appeals for the District of Columbia Circuit ("D.C. Circuit") to review the DEA's ruling. *See Masters Pharmaceutical, Inc. v. DEA* ("*Masters II*") 861 F.3d 206 (D.C. Cir. 2017). Specifically, Masters asserted the Acting Administrator had effectively amended the CSA regulatory scheme by *adding* a new "No-Shipping Requirement" to the list of security requirements in Sections 1301.71 to 1301.76. *See Masters*, 861 F.3d at 221-222. The D.C. Circuit disagreed. It found that in *Southwood*, the DEA had first articulated the No-Shipping Requirement, which "mandates that pharmaceutical companies exercise 'due diligence' before shipping any suspicious order." *Id.* at 221-22.

In reviewing security requirements regarding the maintenance of effective controls against diversion, the D.C. Circuit found that a distributor must comply with two obligations. First, under Section 1301.71(a), it must: (a) "design and operate a system" to identify "suspicious orders of controlled substances" (known as a "Suspicious Order Monitoring System," or "SOMS"), and (b) report those orders to the DEA – this is the Reporting Requirement. *See Masters II*, 861 F.3d at 212. Second, once a distributor has reported a suspicious order, it must either: (1) decline to ship it; or (2) hold the order and conduct some "due diligence" – this is the No-Shipping Requirement. *Id.* If a distributor chooses the latter due diligence option, and it is able to determine the order is

not likely to be diverted into illegal channels, it may then go ahead and ship the order. *Id.* at 212-213 (citing *Southwood*, 72 Fed. Reg. 36487-01, 36,500). Conversely, if a distributor conducts due diligence but is unable to determine the order is not likely to be diverted into illegal channels, it must decline to ship the order. *See id.*

C. DEA Letters.

1. Letter dated September 27, 2006.

On September 27, 2006, the DEA sent all registered distributors a letter "to reiterate the responsibilities of controlled substance distributors in view of the prescription drug abuse problem our nation currently faces." Pls. MSJ on CSA Duties, Ex. B (Doc. #: 1887-4). The letter stressed the importance of distributors' responsibility to maintain appropriate safeguards against diversion. *See id.* at 1-2. Specifically, it stated the requirement to report suspicious orders under Section 1301.74(b) was in addition to – and not in lieu of – the statutory requirement to maintain effective controls against diversion, which included a duty to "exercise due diligence to avoid filling suspicious orders that might be diverted." *Id.* at 2.

The letter further stated as follows:

> It bears emphasis that the [regulatory] reporting requirement is in addition to, not in lieu of, the general requirement . . . that a distributor maintain effective controls against diversion.
>
> Thus, ***in addition to reporting all suspicious orders, a distributor has a statutory responsibility to exercise due diligence to avoid-filling suspicious orders*** that might be diverted into other than legitimate . . . channels. * * *
>
> In a similar vein, given the requirement . . . that a distributor maintain effective controls against diversion, a distributor may not simply rely on the fact that the person placing the suspicious order is a DEA registrant and turn a blind eye to the suspicious circumstances. Again, to maintain effective controls against diversion as section 823(e) requires, the distributor should exercise due care in confirming the legitimacy of all orders prior to filling.

Id. at 2 (emphasis added).

The letter concluded with a list of circumstances that could indicate diversion and questions a distributor might want to ask when determining whether a suspicious order is indicative of diversion. *Id.* at 3. The letter also stated that: (1) these questions were not all-inclusive; (2) answers to the questions would not necessarily determine whether a suspicious order is indicative of diversion; and (3) when evaluating an order for controlled substances, registrants should consider the "totality of the circumstances." *Id.*

2. Letter dated December 27, 2007.

On December 27, 2007, the DEA sent another letter to all registered manufacturers and distributors "to reiterate" their responsibilities to inform the DEA of suspicious orders under Section 1301.74(b). Pls. MSJ on CSA Duties, Ex. C at 1 (Doc. #: 1887-5). The letter stated that, in addition to the general requirement to maintain effective controls against diversion, DEA regulations required all manufacturers and distributors to report suspicious orders "*when discovered* by the registrant." *Id.* (emphasis in original). This letter further stated as follows:

> Registrants are reminded that their responsibility does not end merely with the filing of a suspicious order report. Registrants must conduct an independent analysis of suspicious orders ***prior to completing a sale*** to determine whether the controlled substances are likely to be diverted from legitimate channels. Reporting an order as suspicious will not absolve the registrant of responsibility if the registrant knew, or should have known, that the controlled substances were being diverted. * * *
>
> [R]egistrants that routinely report suspicious orders, yet fill these orders without first determining that order is not being diverted into other than legitimate medical, scientific, and industrial channels, may be failing to maintain effective controls against diversion. Failure to maintain effective controls against diversion is inconsistent with the public interest as that term is used in 21 USC [§§] 823 and 824, and may result in the revocation of the registrant's DEA Certificate of Registration.

Id. at 1-2 (emphasis added).

D. Discovery Ruling No. 12.

On December 9, 2018, in the context of a discovery dispute in this case, Special Master David R. Cohen filed Discovery Ruling no. 12 ("DR-12") (Doc. #: 1174). At that time, defendants were complaining plaintiffs had insufficiently responded to an interrogatory asking plaintiffs to identify defendants' suspicious orders, and explain the criteria plaintiffs used. To understand and explain the obligation that the interrogatory imposed on plaintiffs, the Special Master provided a "short discourse" on the concept of suspicious orders. *Id.* at 1-2.[5]

Highly summarized, the discourse provides as follows: Under Section 1301.74(b), distributors must "design and operate" a system to identify suspicious orders ("SOMS") and report those orders to the DEA, *i.e.* the Reporting Requirement. DR-12 at 2 (Doc. #: 1174) (citing *Masters II*, 861 F.3d at 212 (quoting 21 C.F.R. § 1301.74(b)). Federal regulations explain that "suspicious orders include [among others] orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." 21 C.F.R. § 1301.74(b).[6] A distributor may choose from any number of different methods and algorithms when creating its SOMS.

[5] Because the discourse was written in the context of resolving a discovery dispute, it was not meant to be authoritative or conclusive on how all suspicious ordering systems ("SOMS") must work. *See* Ruling on Motion to Withdraw Portion of Discovery Ruling no. 12 (Doc. #: 1189). Rather, it served the purpose of demonstrating the lack of clarity on whether and when an order meets the definition of "suspicious" − which explained, in turn, why some lack of clarity legitimately existed in plaintiffs' interrogatory response. *Id.* at 3. But the Special Master's explanation accurately sets forth the registrant's duties under the CSA.

[6] The Special Master noted that an order may qualify as suspicious for any number of reasons, including a pharmacy's business model and dispensing patterns. *See* DR-12 at 2-3, n.2 (Doc. #: 1174) (citing *Masters I*, 80 Fed. Reg. 55418-01, 55477).

Having done so, when a distributor identifies an order as suspicious, it must either: (1) decline to ship it; or (2) conduct some "due diligence." DR-12 at 3 (Doc. #: 1174). Regarding the second option, if the distributor is able to determine the order is not likely to be diverted into illegal channels, it may ship the order. Conversely, if the distributor is not able to dispel "all red flags indicative that a customer is engaged in diversion," it must decline to ship the order. *Id.* at 4-7 (quoting *Masters I*, 80 Fed. Reg. 55418-01, 55477).[7]

III. Duties under the CSA.

Plaintiffs ask the Court to determine that, as a matter of law, to meet the requirement of maintaining effective controls against diversion under the CSA and its regulatory scheme, registrants must: (1) design and operate a system to identify suspicious orders; (2) report suspicious orders to the DEA upon discovery; and (3) stop shipment of suspicious orders pending investigation, and not ship them if suspicion remains. Defendants respond that, to the extent the CSA requires such conduct, it does so merely with respect to factors the DEA should consider when determining whether registration is "inconsistent with the public interest," and creates no independent legal duties beyond that context. Defs. Opp. at 4-8 (Doc. #: 2159). Defendants also

[7] The Special Master noted that if a distributor chooses the second option, *i.e.* to investigate, the law is unclear as to *when* the order is deemed "suspicious" and the duty to report arises. DR-12 at 4-7 (Doc. #: 1174) (noting conflicting statements in *Masters II*). In other words, it is unclear whether the distributor must report a suspicious order immediately, *i.e.* before it investigates, or afterwards, *i.e.* only if the investigation fails to dispel the suspicion. *Id.* Plaintiff's motion does not address whether the duty to report arises before or after the due diligence investigation. In any event, the timing of the Reporting Requirement does not impact the No-Shipping Requirement. In other words, regardless of whether a distributor must report a suspicious order before or after investigation, it cannot ship the order unless investigation dispels that suspicion.

assert the CSA imposes no requirement for registrants to stop shipment of suspicious orders pending investigation. *Id.* at 8-21. The Court examines these assertions below.

A. Duty to Identify and Report Suspicious Orders (Reporting Requirement).

Plaintiffs assert that Section 1301.74 imposes a legal obligation on registrants to identify and report suspicious orders to the DEA, *i.e.* the Reporting Requirement. As noted, the regulation states that all registrants "shall design and operate a system to disclose to the registrant suspicious orders of controlled substances" and "shall inform the [DEA] of suspicious orders when discovered by the registrant." 21 C.F.R. § 1301.74(b).

Defendants assert the Reporting Requirement arises only in the context of factors that the DEA may consider in the registration process and creates no "legal duties" *that would trigger liability to plaintiffs*. Defs. Opp. at 4-8 (Doc. #: 2159). Plaintiffs' motion, however, seeks only a legal determination regarding a registrant's duties under the CSA and its regulatory scheme; plaintiffs do not ask the Court to address the scope of possible liability for breach of those duties. More important, Section 821 authorizes the DEA to promulgate rules and regulations "relating to the registration *and control"* of the manufacture and distribution of controlled substances. 21 U.S.C. § 821 (emphasis added). Thus, the CSA regulatory duties do not arise solely in the context of the registration process, as defendants assert. In other words, defendants are correct that the CSA sets out "factors" the DEA must weigh when determining whether a business may be or remain a "registrant" that can manufacture or distribute controlled substances, but the CSA *also* sets out, as a matter of law, duties that registrants must shoulder in order that adequate controls are maintained over controlled substances.

The plain language of Section 1301.74 clearly requires that, upon discovery, registrants must identify and report suspicious orders to the DEA. *See* 21 C.F.R. § 1301.74; *Masters II*, 861 F.3d at 212. As a regulation promulgated pursuant to Congressional authority, Section 1301.74 is legislative in nature and has the full force and effect of law. *See Chevron USA, Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837, 843-844 (1984) (as long as a federal agency regulation is based on permissible construction of the enabling statute, the regulation should be enforced); *Chrysler Corp. v. Brown*, 441 U.S. 281, 295 (1979) (properly promulgated substantive agency regulations have the force and effect of law); *Nichols v. United States*, 260 F.3d 637, 648 (6th Cir. 2001) (regulations promulgated pursuant to Congressional authority are legislative in nature and have the force and effect of law). Accordingly, the Court finds that, as a matter of law, Section 1301.74 imposes a legal duty on registrants to: (1) design and operate a system to disclose to the registrant suspicious orders; and (2) inform the DEA of suspicious orders when discovered by the registrant.[8] *See* 21 C.F.R. § 1301.74; *Masters II*, 861 F.3d at 212.

B. Duty to Not Ship Suspicious Orders (No-Shipping Requirement).

The duties to identify and report suspicious orders are explicit. Plaintiffs assert the CSA and its regulatory scheme also necessarily impose a legal obligation on registrants to stop shipment of suspicious orders pending a due diligence investigation into whether the order is likely to be diverted, *i.e.* the No-Shipping Requirement. Specifically, plaintiffs assert this duty necessarily arises from the statutory and regulatory obligations to maintain effective controls against diversion

[8] The Court notes that determining whether a specific order is "suspicious" and the timing of when it is "discovered" involve questions of fact that will necessarily depend on the totality of individual circumstances.

of controlled substances into illegitimate channels. Pls. Mem. on CSA Duties at 3-7 (Doc. #: 1887-1) (citing 21 U.S.C. § 823; 21 C.F.R. § 1301.71(a)); *see also* Pls. Reply at 8-9 (Doc. #: 2466). As noted, Section 821 authorizes the DEA Administrator to promulgate rules and regulations "relating to the registration *and control*" of the manufacture and distribution of controlled substances.[9] 21 U.S.C. § 821 (emphasis added). Pursuant to this authority, the DEA Administrator has promulgated Section 1301.71(a), which requires all registrants to "provide effective controls and procedures to guard against theft and diversion of controlled substances." 21 C.F.R. § 1301.71(a).

Defendants assert that, to determine whether a registrant has maintained effective controls, the Administrator can use only the security requirements set forth in Sections 1301.72 to 1301.76, which do not explicitly require registrants to investigate orders or halt shipments. Defs. Opp. at 7-8 (Doc. #: 2159). Section 1301.71(a) states that "[i]n order to determine whether a registrant has provided effective controls against diversion, the Administrator shall use the security requirements set forth in §§ 1301.72 − 1301.76 as standards for the physical security controls and operating procedures necessary to prevent diversion." 21 C.F.R. § 1301.71(a). Although the regulation requires the Administrator to use the security requirements set forth in Sections 1301.72 to 1301.76, it does not state those requirements are exclusive or that the Administrator cannot consider other factors in this regard. *See* 21 C.F.R. § 1301.71(a). As a regulation promulgated pursuant to Congressional authority, Section 1301.71 carries the full force and effect of law. *See Chevron*, 467 U.S. at 843-844; *Chrysler*, 441 U.S. at 295; *Nichols*, 260 F.3d at 648. Section

[9] In addition, Section 823 provides that, in determining the public interest, the DEA Administrator shall consider, *inter alia*, the "maintenance of effective control against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels." 21 U.S.C. §§ 823(b)(1), (d)(1), and (e)(1).

1301.71 plainly requires registrants to provide effective controls and procedures to guard against the diversion of controlled substances, and it does not limit those controls and procedures to only the security requirements enumerated in the regulations.[10] *See* 21 C.F.R. § 1301.71.

Defendants assert that neither the CSA nor its regulations articulate a no-shipping duty. But as discussed above, in *Masters II* the D.C. Circuit found that the DEA did articulate a No-Shipping Requirement in *Southwood;* and this requirement mandates that, once a distributor has discovered a suspicious order, it must either: (1) decline to ship the order; or (2) conduct "due diligence" to determine whether the order is likely to be diverted into illegal channels. *Masters II*, 861 F.3d at 212-213, 222. The Court has carefully reviewed the supporting authorities and fully agrees with the D.C. Circuit's analysis in this regard.[11]

In addition, having reviewed the Special Master's Discovery Ruling No. 12 in the context of the parties' summary judgment briefings, the Court finds it clearly and accurately describes the extent of the defendants' duties under the CSA and its regulations, and when those duties do and

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[10] To the extent defendants assert the question of whether a registrant is maintaining effective controls against diversion is only a factor the DEA may consider relative to registration, and not a duty imposed by the statute, the Court rejects this argument for reasons stated above.

[11] Defendants assert the *Masters II* analysis was not material to its holding and provides "no legal support" for plaintiffs' assertion that the CSA imposes a requirement to not ship suspicious orders. Defs. Opp. at 21 (Doc. #: 2159). The Court disagrees. Even if the D.C. Circuit's analysis regarding the No-Shipping Requirement was dicta, the Court finds it well-reasoned and highly persuasive. *See*, *e.g.*, *PDV Midwest Ref., LLC v. Armada Oil & Gas Co.*, 305 F.3d 498, 510 (6th Cir. 2002) (even if the Second Circuit's discussion regarding voluntary loss of trademark was dicta, its analysis of the issue was well-reasoned and persuasive); *Wright v. Morris*, 111 F.3d 414, 419 (6th Cir. 1997) (dicta by Supreme Court cannot be dismissed out of hand; where there is no clear precedent to the contrary, the court will not simply ignore the Supreme Court's dicta); *Holden v. Brown*, 668 F. Supp. 1042, 1047 (N.D. Ohio 1986) (the court is obliged to defer to and adopt Sixth Circuit dicta unless clearly persuaded that the appellate court erred).

do not arise.[12] *See* DR-12 at 2-7 (Doc. #: 1174). Specifically, the Court fully agrees with Special Master Cohen's conclusion that, based on the CSA statutory and regulatory requirements, "it is clear that distributors are required to identify suspicious orders from pharmacies and cannot ship those orders unless investigation [first] shows them to be legitimate." *Id.* at 7.

The DEA's adjudicative decisions in *Southwood* and *Masters I* provide further support for the Court's conclusion. Defendants assert that the agency adjudications are case-specific, relate only to revocation of the registration of two non-party companies, and do not impose legal requirements on other registrants. Defs. Opp. at 18-20 (Doc. #: 2159). The Court disagrees. Federal agencies exercise broad discretion to carry out their statutory mandate through adjudication and to announce policies or principles that may affect non-parties. *See Citizens for Responsibility & Ethics in Washington v. FEC*, 164 F. Supp.3d 113, 118-119 (D.C. Cir. 2015); *PDK Labs. Inc. v. DEA.*, 438 F.3d 1184, 1195 (D.C. Cir. 2006) (when a statute confers broad discretionary authority, the DEA may establish contours of the law through a series of adjudications); *see also* 21 U.S.C. § 824 (proceedings to deny, revoke, or suspend registration shall be conducted pursuant to the Administrative Procedure Act, subchapter II of chapter 5 of Title 5). Accordingly, the Court rejects defendants' arguments that the principles announced in agency adjudications do not apply to them.

In sum, the Court concludes that the CSA statutory and regulatory duties to maintain effective controls against diversion includes a duty not to ship suspicious orders.[13] Indeed, given

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[12] The Court therefore adopts the analysis in DR-12 for purposes of analyzing the plaintiffs' present motions, in addition to having already adopted it in the context of resolving a discovery dispute, and incorporates all of it herein by reference.

[13] In reaching this result, the Court does not rely on the DEA letters of 2006 and 2007, and instead relies simply on the language of the statute and regulations themselves, as interpreted by federal courts. The Court notes, however, that the DEA's statements in the letters are wholly

the overriding duty of a registrant to maintain effective controls against diversion, the Court is hard-pressed to think of a more basic requirement than not to ship a dubious order bearing indicia that the drugs could be diverted to illegal channels. How can a registrant freely ship suspicious orders and still comply with its duty to maintain controls against diversion? It cannot. It has a duty not to ship the order unless due diligence reasonably dispels the suspicion.

IV. Defendants' Compliance with their CSA Duties.

Plaintiffs' second motion for summary judgment builds on their first motion: Plaintiffs assert that, not only does the CSA impose upon the defendants three duties as a matter of law—the Identification Requirement, the Reporting Requirement, and the No-Shipping Requirement—but the Court must conclude, as a matter of undisputed fact, that each defendant failed to meet these duties.

Specifically, plaintiffs seek partial summary judgment asking the Court to rule, as a matter of law, that during the period 2000-2016, with respect to opioid orders shipped to Summit and Cuyahoga Counties, Defendants failed to comply with their duties under the CSA to design and operate a system to identify suspicious orders, report suspicious orders to the DEA, and/or halt shipment of suspicious orders pending investigation. Pls. Mem. on Compliance at 25-26, 143 (Doc. #: 1910-1). Plaintiffs also assert that, as a matter of law, Defendants violated 21 U.S.C. § 843(a)(4)(A), which provides that a registrant violates the CSA when it knowingly or intentionally

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consistent with this Court's conclusion. In the letters, the DEA "reiterated" to all registrants that to comply with their duty to maintain effective controls against diversion, they must exercise due diligence and avoid shipping suspicious orders. Pls. MSJ on CSA Duties, Exs. B and C (Docs. ##: 1887-4, 1887-5).

furnishes false information and/or omits material information regarding suspicious orders in documents required to be made, kept, or filed under the CSA. Pls. Mem. on Compliance at 22-23 (Doc. #: 1910-1). As discussed below, the Court concludes material facts are in dispute, so plaintiffs' second motion for summary judgment is not well-taken.

V. Analysis.

Plaintiffs and defendants acknowledge that Section 832(a)(1) of the CSA requires each registrant to design its own SOMS. However, the parties do not agree on what constitutes an effective SOMS as to each Defendant.

Plaintiffs' Motion sets forth, in great detail, "undisputed evidence" that each Defendant "repeatedly and consistently manufactured, sold, and/or shipped opioids in violation of their CSA obligations." *Id.* at 25. In their Response Briefs, both Manufacturer and Distributor Defendants argue Plaintiffs cannot prove and have not shown, as a matter of law and undisputed fact, that the SOMS used by each Defendant was inadequate under the CSA. *See* Man. Opp. on Compliance (Doc. #: 2097); Dist. Opp. on Compliance (Doc. #: 2149). Defendants provide specific, factual evidence to support their argument that each Defendant complied with its obligations under the CSA. Defendants further argue that whether each Defendant maintained an effective SOMS as a control against diversion presents a genuine issue of material fact, and therefore, summary judgment is not warranted.

The Court has carefully reviewed the evidence presented by the parties, in the light most favorable to Defendants, see *Williams v. Mehra*, 186 F.3d 685, 689 (6th Cir. 1999), and finds the record is replete with disputes of material fact as to whether each Defendant complied with its obligations under the CSA, which preclude summary judgment. In these circumstances, it is a jury

that must determine the credibility of the evidence, the weight to be given to the evidence, and any inferences to be drawn from the facts presented. *See Yazdian v. ConMed Endoscopic Technologies, Inc.,* 793 F.3d 634, 644 (6th Cir. 2015) (citing *Anderson,* 477 U.S. at 255). Put simply, while the Defendants had a duty not to ship suspicious orders, there are disputes of fact as to whether, and when, each Defendant's SOMS was adequate, whether orders were suspicious, and whether each Defendant did actually ship suspicious orders (or instead, identified it as suspicious but then, through due diligence, dispelled that suspicion).[14]

By way of illustration, the Court provides below examples of specific factual disputes with respect to two Manufacturer Defendants (Mallinckrodt and Purdue) and two Distributor Defendants (Cardinal and McKesson). Similar factual disputes are present for every other Defendant addressed in the parties' briefs.

A. Manufacturer Defendants.

1. **Factual Assertions Regarding Mallinckrodt.**

Plaintiffs allege Mallinckrodt failed to comply with its duties under the CSA to maintain effective controls against diversion.[15] Specifically, Plaintiffs allege Mallinckrodt's SOMS was

[14] Plaintiffs contend they "need only establish that during portions of the relevant time period, Defendants failed to establish and maintain compliant programs." Pls. Reply at 2 (Doc. #: 2466). Plaintiffs, however, have not attempted to define which portions of time they contend defendants were in violation, or what time periods are relevant to their claims in this case. *See, e.g., id.* at 40, 44 (before 2006, McKesson's system would not disclose suspicious orders of generic opioids; Cardinal did not adopt a "do not ship" policy until after January 2008).

[15] Plaintiffs argue that Mallinckrodt "admitted" it failed to maintain a proper SOMS in a 2017 agreement between Mallinckrodt and the DEA. See Pls. Mem. on Compliance at 27 (Doc. #: 1910-1). Construed in a light most favorable to Mallinckrodt, the record evidence does not support Plaintiffs' argument.

improper under the CSA because: (1) it utilized an inadequate numeric "threshold formula" as the foundation of its SOMS; (2) it failed to identify and report suspicious orders to the DEA; and (3) it failed to use available "chargeback data" to control against diversion. Pls. Mem. on Compliance at 27-37 (Doc. #: 1910-1).

a. Threshold Issue.

Plaintiffs claim Mallinckrodt's SOMS was improperly based upon a rigid numerical formula, whereby "if an order did not exceed the threshold set by Mallinckrodt's numeric formula, it was not flagged as 'peculiar' and therefore not examined at all." *Id.* at 29. To support this argument, Plaintiffs cite to a DEA Memorandum issued in 2007, deposition testimony from members of Mallinckrodt's compliance department, and a report from an independent consultant hired by Mallinckrodt to review its SOMS.[16]

However, Mallinckrodt argues its SOMS program has "always included both an algorithm and non-algorithm components," and provides a specific list of the "comprehensive range of additional tools, procedures, and systems [used] to flag potentially suspicious orders." Man. Opp. on Compliance at 15-16 (Doc. #: 2097). Clearly, the parties rely on conflicting factual information and data to argue their positions relating to Mallinckrodt's SOMS. This evidence results in a conflict of material fact to be resolved by a jury. *See Crespo v. U.S. Merit Systems Protection Bd.*, 486 F.Supp.2d 680, 689 (N.D. Ohio 2007) (*citing Cox v. Kentucky Dept. of Transp.*, 53 F.3d 146, 148 (6th Cir. 1995).

b. Failure to Identify and Report Suspicious Orders

[16] See Pls. Mem. on Compliance at 28-30 (Doc. #: 1910-1).

Plaintiffs claim Mallinckrodt's SOMS was inadequate because it failed to properly identify and report suspicious orders to the DEA. First, Plaintiffs claim that "between 2003 and 2011, Mallinckrodt shipped more than 53 million orders of opioid products," identified 37,817 orders as potentially suspicious, but "only stopped – at most – 33 orders and reported them to the DEA." Pls. Mem. on Compliance at 30-31 (Doc. #: 1910-1).[17] Plaintiffs argue these numbers "speak for themselves" to illustrate Mallinckrodt's ineffective SOMS: during "the height of the opioid crisis, Mallinckrodt encountered only 33 suspicious orders out of 53 million." *Id.* at 31.

Mallinckrodt provides contradictory factual evidence, claiming that between 2003 and 2011, Mallinckrodt "shipped fewer than 1 million orders of opioid products." Man. Opp. on Compliance at 17 (Doc. #: 2097). Furthermore, Mallinckrodt states "there is no evidence that Mallinckrodt shipped *any* opioid products to either Bellwether county at *any* time." *Id.* at 14. Plaintiffs reply that, despite Mallinckrodt's semantics regarding whether it "shipped" opioids into the Counties, Mallinckrodt does not appear to dispute that it *manufactured* approximately 25% of the opioids (2.3 billion MMEs) supplied to the Bellwether jurisdictions between 2006 to 2014. *See* Pls. Reply at 22-23 (Doc. #: 2466). Clearly, the parties' conflicting and divergent factual data present genuine issues of material fact better left to a jury. *See*, *Crespo*, 486 F.Supp.2d at 689.

Plaintiffs also attack Mallinckrodt's SOMS for other reasons, claiming Mallinckrodt shipped potentially suspicious orders prior to completing due diligence, Mallinckrodt's SOMS failed to evaluate whether an order was of unusual size, frequency, or deviated substantially from

[17] Plaintiffs do not make it clear if they claim any or all of the alleged 53 million orders were shipped to the Plaintiff counties, nor do they provide a source to support the claim that 33 orders were reported or stopped. That said, Mallinckrodt does not dispute that it only stopped 33 orders.

normal patterns,[18] and Mallinckrodt's decision to rely upon its sales representatives to determine which order to ship was contrary to its obligations under the CSA. Pls. Mem. on Compliance at 30-35 (Doc. #: 1910-1). Mallinckrodt refutes these claims, citing to sworn testimony provided by several employees with knowledge of the implementation of Mallinckrodt's SOMS and its alleged effectiveness. Man. Opp. on Compliance at 16-19 (Doc. #: 2097). These are significant factual issues to be determined by a jury.

c. Chargeback Data Issue.

Plaintiffs claim Mallinckrodt failed to maintain effective controls against diversion when it ignored detailed information it possessed, in the form of "chargeback data,"[19] which gave Mallinckrodt "visibility into the entire supply chain for its products, from manufacturer to distributor to pharmacies and other end users."[20] Plaintiffs claim that, if Mallinckrodt had utilized this chargeback data, it would have easily identified more suspicious orders, "problem pharmacies," and other red flags for diversion. Pls. Mem. Compliance at 35-37 (Doc. #: 1910-1).

Mallinckrodt argues it was under no obligation to use chargeback data as part of its SOMS under the CSA, claiming that the "DEA has never once issued a notice to manufacturers informing them that they must monitor orders their distributor customers receive from their (distributors')

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[18] Plaintiffs claim that Mallinckrodt's SOMS "consisted *solely* of verifying DEA 222 forms" from 2008-2009. Pls. Mem. on Compliance at 31 (Doc. #: 1910-1) (emphasis in original).

[19] Mallinckrodt defines "chargeback data" as a financial reconciliation mechanism whereby, under the terms of a contract between manufacturer and distributor, the distributor requests a chargeback when the distributor has sold the manufacturer's product for less than what the distributor paid for it.

[20] Plaintiffs claim this chargeback data also provided Mallinckrodt with the pharmacy name, DEA registration number, and address, as well as the quantity of opioid products sold to that pharmacy. Pls. Mem. on Compliance at 35 (Doc. #: 1910-1).

own pharmacy customers."[21] Man. Opp. on Compliance at 9 (Doc. #: 2097). Moreover, Mallinckrodt claims there is evidence that it "*did* use chargeback data in developing its groundbreaking and innovative efforts to prevent downstream diversion," and it shared its methods of examining downstream transactions with the DEA. *Id.* at 19. In order to resolve the issue of whether Mallinckrodt used chargeback data properly, or not at all, in order to fulfill its duty to prevent diversion, requires an evaluation of specific factual evidence by a jury.

2. **Factual Assertions Regarding Purdue**

Plaintiffs argue that Purdue failed to comply with its duties under the CSA to maintain and operate a SOMS to identify, report, and stop the shipment of any suspicious orders of its opioid products. Pls. Mem. on Compliance at 37 (Doc. #: 1910-1). While the parties agree that Purdue created its first SOMS[22] in the early 2000s,[23] there are material fact issues as to whether that SOMS was adequate under the CSA.

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[21] This Court has indicated that the CSA regulations are "not so limiting," and do "not state that a registrant's obligation to report suspicious orders applies only to orders from its direct customers." *In re National Prescription Opiate Litigation,* 1:17-md-2804, 2018 WL 4895856, at *22 (N.D. Ohio Oct. 5, 2018). Manufacturer Defendants assert that Plaintiffs are "attempting to invent new legal obligations" under the CSA that would require a Manufacturer of opioids to monitor and report downstream transactions of its customers' customers," but Plaintiffs do not request a finding as a matter of law on that issue. *See* Man. Opp. on Compliance at 7 (Doc. #: 2097). The fact that Mallinckrodt had chargeback data and could have used it to identify suspicious orders is relevant, even if Mallinckrodt was not obligated to do so by the DEA.

[22] Purdue referred to their SOMS as the "suspicious order standard operating procedure," or "SOPS."

[23] *See* Pls. Mem. on Compliance at 37 (Doc. #: 1910-1); Man. Opp. on Compliance at 24 (Doc. #: 2097).

For instance, Plaintiffs claim Purdue had access to very specific information[24] regarding the sale and distribution of Purdue's opioids from distributors to individual pharmacies, which allowed Purdue to generate a list of "Region 0" prescribers "considered to be potential diverters," but Purdue did not report these potential diverters or stop supplying them with opioids. *Id.* at 39-40. Purdue responds it "was 'routinely' in communication with the DEA and distributors about potentially suspect pharmacy accounts," and while Purdue argues it had no duty to "monitor and report downstream activity," Purdue claims it *did* report dozens of "downstream customers" to the DEA. Man. Opp. on Compliance at 26-27 (Doc. #: 2097).[25] As this Order has made clear, the evaluation of chargeback data, and whether such data should and could have been used to prevent diversion, is a fact question for the jury.

Plaintiffs also claim Purdue's SOMS was "financially motivated" and there were not enough qualified employees monitoring potentially suspicious orders. Pls. Mem. on Compliance at 37-38 (Doc. #: 1910-1). Purdue rebuts this argument with a specific list of "steps taken and factors considered by Purdue when reviewing a held order"[26] to argue it did engage in due diligence

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[24] Plaintiffs claim Purdue entered into agreements with distributors whereby Purdue paid its distributors to provide "chargeback data," which provided Purdue with information as to the size, pattern, and frequency of most orders of Purdue opioids delivered to pharmacies and other dispensers. Purdue claims this data was more limited and not available in real-time. *See* Man. Opp. on Compliance at 25-26 (Doc. #: 2097).

[25] Despite Purdue's assertion that it had no duty to monitor its customers' customers, in 2008 it expanded its SOMS to "help its direct customers (*i.e.*, wholesalers and distributors) monitor their customers (*i.e.*, retail pharmacies) by putting in place an Order Monitoring System ("OMS")." Man. Opp. on Compliance at 23 (Doc. #: 2097).

[26] Purdue asserts these steps included reviewing the customer's ordering patterns; reviewing overall sales for the account; considering whether the customer was a regional distribution center; considering the strength of OxyContin ordered; consulting with the manager responsible for the account; communicating directly with the customer; and determining if there were any changes in health coverage to the area. Man. Opp. on Compliance at 24-25 (Doc. #: 2097).

before releasing orders. Man. Opp. on Compliance at 24-25 (Doc. #: 2097). These issues also require an in-depth review of factual evidence by a jury.

B. Distributor Defendants.

1. Factual Assertions Regarding Cardinal.

Plaintiffs assert generally that Cardinal violated its duties under the CSA in two respects: (1) prior to 2008, by not having any system in place to timely report suspicious orders or prevent shipment of suspicious orders; and (2) between 2012 and 2015, by failing to report more than 14,000 suspicious orders, at least four of which originated in Summit and/or Cuyahoga Counties.[27] Pls. Mem. on Compliance at 69-78 (Doc. #: 1910-1).

a. Lack of SOMS Prior to 2008.

Plaintiffs present factual evidence that, prior to 2008, Cardinal did not have a system in place to timely report suspicious orders or prevent shipment of suspicious orders. Rather, during this period, at the end of each month, Cardinal distribution centers merely created Ingredient Limit Reports ("ILR"), which listed customers whose total orders exceeded the limit for that drug base code. *Id.* at 76. Cardinal considered these orders suspicious but did not conduct due diligence and only reported the orders after they had shipped. *Id.* at 77.

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[27] Plaintiffs also present several pages of facts which they contend show the "mindset" of Cardinal which led to its failure to comply with CSA duties. See Pls. Mem. on Compliance at 69-75 (Doc. #: 1910-1). Defendants dispute plaintiffs' assertions. *See, e.g.,* Dist. Opp. on Compliance at 24-28 (Doc. #: 2149). Regardless, the asserted facts do not establish that, as a matter of law, Cardinal violated the CSA with respect to plaintiffs' claims in this case.

Conversely, Cardinal presents evidence that, from the 1990s through at least 2007, it operated a SOMS under which it submitted monthly ILRs and Excessive Order reports to the DEA. Dist. Opp. on Compliance at 19-20 (Doc. #: 2149). During this time, DEA investigators viewed such reports as compliant with the CSA. *Id.* at 20, 21 n.53. Cardinal asserts that, in 2007, the DEA changed its interpretation of the law and for the first time announced that submitting ILRs would not satisfy the suspicious order reporting requirement.[28] *Id.* at 21-22. The sum of evidence presented shows material facts in dispute that must be resolved by a jury.

b. Failure to Report Orders to the DEA.

Plaintiffs present evidence that, between 2012 and 2015, Cardinal Health failed to report more than 14,000 suspicious orders. Pls. Mem. on Compliance at 77-78 (Doc. #: 1910-1). Plaintiffs assert that at least four of these orders were from customers in Summit and/or Cuyahoga Counties. *Id.*

Cardinal concedes that, from 2012 to 2015, it inadvertently failed to report 14,000 orders to the DEA, but asserts it did not ship any of these orders. Dist. Opp. on Compliance at 28 n.56, 29 (Doc. #: 2149). Cardinal indicates that, of these 14,000 orders, only four orders originated in

[28] In response to Plaintiff's Motion, the Distributor Defendants admit that, at least since 2007, the DEA has imposed a no-shipping requirement on distributors. Specifically, Defendants state that in 2007, the DEA "markedly changed its guidance . . . [and] adopted a 'no ship' requirement," which it first announced to registrants in its letter dated December 27, 2007. Dist. Opp. on Compliance at 22 (Doc. #: 2149)).

Plaintiffs agree the DEA letter "clearly and undisputedly put the defendants − both manufacturers and distributors − on notice of their obligations under the CSA." Pls. Mem. on Compliance at 8 (Doc. #: 1910-1). In addition, plaintiffs' factual assertions confirm a shift in some defendants' SOMS policies beginning around 2007. *See id.* at 72, 92 (Cardinal did not have policy to stop shipment until 2008; 2007 marked a key shift in AmerisourceBergen's SOMS policies).

Summit and/or Cuyahoga Counties. *Id.* at 29. In April of 2018, Cardinal informed the DEA that its automated reporting system failed to transmit the information to the DEA. *See id.*

Construed in a light most favorable to Cardinal, the record presents genuine issues of material fact regarding: (1) whether Cardinal operated a SOMS which effectively identified suspicious orders under the circumstances; (2) whether Cardinal identified or should have identified any suspicious orders regarding the subject counties, and if so, how many and when; (3) with respect to any such suspicious orders, whether Cardinal performed due diligence, and if so, whether the investigation was adequate under the circumstances; (4) whether Cardinal's due diligence cleared or would have dispelled the suspicion; (5) whether Cardinal actually shipped any suspicious orders to the subject counties, and if so, how many and when; and (6) whether Cardinal "*substantially*" complied with its duties under the CSA.

2. Factual Assertions Regarding McKesson.

Plaintiffs assert McKesson failed to maintain an effective SOMS both before and after 2008, and that it entered into a 2008 settlement with the DEA that demonstrates it violated its duties under the CSA.

a. Lack of SOMS Before 2008.

Plaintiffs assert that, before 2008, McKesson utilized a SOMS that only *retrospectively* reported sales of controlled substances that exceeded certain thresholds. Pls. Mem. on Compliance at 79 (Doc. #: 1910-1). Plaintiffs contend the SOMS did not flag truly suspicious orders and McKesson performed no due diligence and did not block shipment of suspicious orders. *Id.* at 79-80. McKesson counters with evidence that during this time, the DEA accepted its SOMS and manner of reporting as compliant and the DEA did not impose a no-ship requirement Dist. Opp. on Compliance at 37-39 (Doc. #: 2149). These facts present issues for a jury determination.

b. Settlement Agreement with DEA.

Plaintiffs observe McKesson entered into a settlement agreement with the DEA and assert this demonstrates as a matter of law that McKesson violated its duty to maintain effective controls against diversion. Specifically, plaintiffs assert that, in May of 2008, McKesson agreed to pay to DEA a fine of $13,250,000 for alleged violations of the CSA regarding distribution of opioids. Pls. Mem. on Compliance at 81-82 (Doc. #: 1910-1). The settlement, however, involved McKesson distribution centers located in Florida, Maryland, Texas, Colorado, Utah, and California. See Plaintiffs' MSJ on Compliance, Ex. 249, (Doc. #1964-36). Moreover, under the terms of settlement, McKesson denied the allegations. *See* Dist. Opp. on Compliance at 40-41 (Doc. #: 2149). On this record, Plaintiffs have not shown the settlement conclusively proves McKesson violated its legal duties with respect to opioid shipments into Summit and Cuyahoga Counties.

c. SOMS from 2008 to 2014.

Plaintiffs assert that, in 2008, McKesson implemented a new SOMS which involved a three-level review process once a customer triggered its monthly threshold; but from 2008 to 2014, McKesson did not actually perform second or third level reviews for customers in Summit and Cuyahoga Counties. Pls. Mem. on Compliance at 82-83 (Doc. #: 1910-1). Plaintiffs contend that, although the SOMS established a process for blocking shipments, the SOMS contained many loopholes, and McKesson set extremely high thresholds and routinely increased thresholds without adequate justification. *Id.* at 83-85.

McKesson responds that, if a customer placed an order above its threshold, McKesson flagged the order and stopped shipment pending further investigation. Dist. Opp. on Compliance

at 33 (Doc. #: 2149). McKesson presents evidence to support its assertion that it only increased a customer's threshold based upon a legitimate change in circumstances. *Id.* at 35. McKesson further asserts that, in establishing the new SOMS, it worked closely with the DEA, which specifically instructed it to only report orders after it had completed due diligence and determined it would not complete the sale because the order was suspicious. *Id.* at 37-38.

Clearly, the parties' evidence on these issues presents factual disputes. On this record, Plaintiffs have not shown that, as a matter of law and undisputed fact, defendants violated their duties to maintain effective controls with regard to opioid shipments into Summit and Cuyahoga Counties.

VI. Furnishing False Information.

The CSA makes it unlawful to knowingly or intentionally furnish false or fraudulent material information in, or omit any material information from, any application, report, record, or other document required to be made, kept or filed under the statute. 21 U.S.C. § 843(a)(4)(A). Plaintiffs claim that, to the extent "Defendants failed to report to the DEA orders they knew or should have known were suspicious, they either furnished false information or omitted material information" in the reports provided. Pls. Mem. on Compliance at 22 (Doc. #: 1910-1). Plaintiffs also claim that, to the extent "Defendants reported suspicious orders, but omitted from their reports the fact that the suspicious orders had been shipped without any due diligence investigation," the reports omitted material information. *Id.* at 22-23.

Plaintiffs do not specifically address this argument in the rest of their brief, except perhaps to assert that in some instances, Defendants knew or should have known their conduct violated

their duties under the CSA. Similarly, Defendants do not address this claim in their Response Briefs. In any event, the Court finds the record is replete with material factual disputes regarding whether Defendants furnished false information or omitted material information, and, if so, whether they did so knowingly or intentionally.

Accordingly, this Court denies Plaintiffs Motion for Partial Summary Adjudication that Defendants failed to comply with their duties under the CSA.

IT IS SO ORDERED.

/s/ Dan Aaron Polster 8/19/19
DAN AARON POLSTER
UNITED STATES DISTRICT JUDGE